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THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US60/588,878*

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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INVENTOR(S)

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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

Hip Interposition Arthroplasty

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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OR

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☐ Specification *Number of Pages* 3

☐ Drawing(s) *Number of Sheets* 1

☐ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number

☒ Other (specify) Return Postcard

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check or money order is enclosed to cover the filing fees

☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($)

$80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Jeffrey C Felt

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Date July 16 04

REGISTRATION NO. *(if appropriate)*

Docket Number: 32355.12.36

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

Introduction to Hip Patent

The normal hip functions through a wide range of motion and supports loads several times the body weight in the activities of daily living. Articular cartilage on both surfaces of the hip joint aids in absorbing impact, distributing load, maintaining alignment and minimizing friction. In patients with osteoarthritis, the articular cartilage is thinned or completely eliminated and these four attributes are lost. The result for the patient with this condition is pain that may become disabling. The current treatment for painful osteoarthritis of the hip that is unresponsive to medical therapy is total hip replacement. This procedure involves removal of the femoral head and the insertion of a metal stem into the shaft of the femur. The stem is usually capped with a Morris Taper junction metallic ball. On the acetabular side of the joint, a metal cup lined with Ultra High Molecular Weight Polyethelene (UHMWPE) is inserted into the pelvic bone. The cup and stem are usually affixed with a Polymethyl Methacrolate (PMMA) grout or may have a bone in-growth fixation.

A less invasive, non-bone cutting procedure employing an implant that restores the functions of articular cartilage would be an important alternative for patients with severe osteoarthritis of the hip.

Claims

1. A polymeric interpositional arthroplasty positioned in the acetabulum to provide a wear and load bearing surface in an arthritic hip joint.

2. An implant as described in claim 1 that can be placed by minimally invasive surgical techniques or with a larger exposure.

3. An implant as described in claim 1 wherein the polymeric material is a biomaterial of between 55A and 100D durometer including but not limited to PEEK, polyurethane, polyethylene, etc.

4. An implant as described in claim 1 wherein the polymer is one of several polyurethanes described by previous ABS patent numbers 6,140,452 and 6,652,587.

5. A polymeric interpositional hip arthroplasty wherein the implant is composed of one or more than one durometer polyurethane or other polymeric biomaterial.

6. An implant as in claim 5 wherein the device has the configuration resembling the acetabulum to fit between the acetabulum and the femoral head.

7. An implant as in claim 6 where the device has an opening or depression to accommodate the ligament of the head of the femur.

8. An implant as in claim 7 wherein the major load bearing area of the device is composed of a high durometer, wear resistant polyurethane and the remaining half is composed of a softer durometer, more compliant polyurethane. In an alternative embodiment, a single durometer material may be used.

9. An implant as in claim 8 wherein the compliant portion of the device allows the implant to be folded for insertion through a minimally invasive surgical incision. (See drawings.)

10. An implant as described in claim 9 that would allow insertion through a small (i.e., 4 cm) incision following arthroscopic preparation of the joint.

11. An implant as described in claim 10 wherein the device is shaped to be congruent with the major anatomical features of the acetabulum.

12. An implant as described in Claim 11 wherein the device has a series of anchors (1-5) of barbed polyurethane to insert into predrilled holes and press-fit into the acetabulum.

13. An implant as described in claim 11 wherein the softer durometer material portion has an enlargement on the acetabular surface that fits into the fovea and provides added rotational stability to the implant.

14. An implant as described in claim 12 wherein the device has tabs or fabric around the rim to provide for suture fixation or tissue in-growth to enhance stability.

15. In the preferred embodiment, the implant as in claim 12 may be inserted and deployed with or without dislocating the hip. An external distracter to get enough joint space may be used.

16. An implant as described in claim 10 wherein the device is supplied in multiple sizes.

17. An insertion tool that allows placement of the implant through a mini-incision. (See drawing.)

18. A deployment tool that allows the surgeon to unfold the implant and seat it in the acetabulum. (See drawing.)

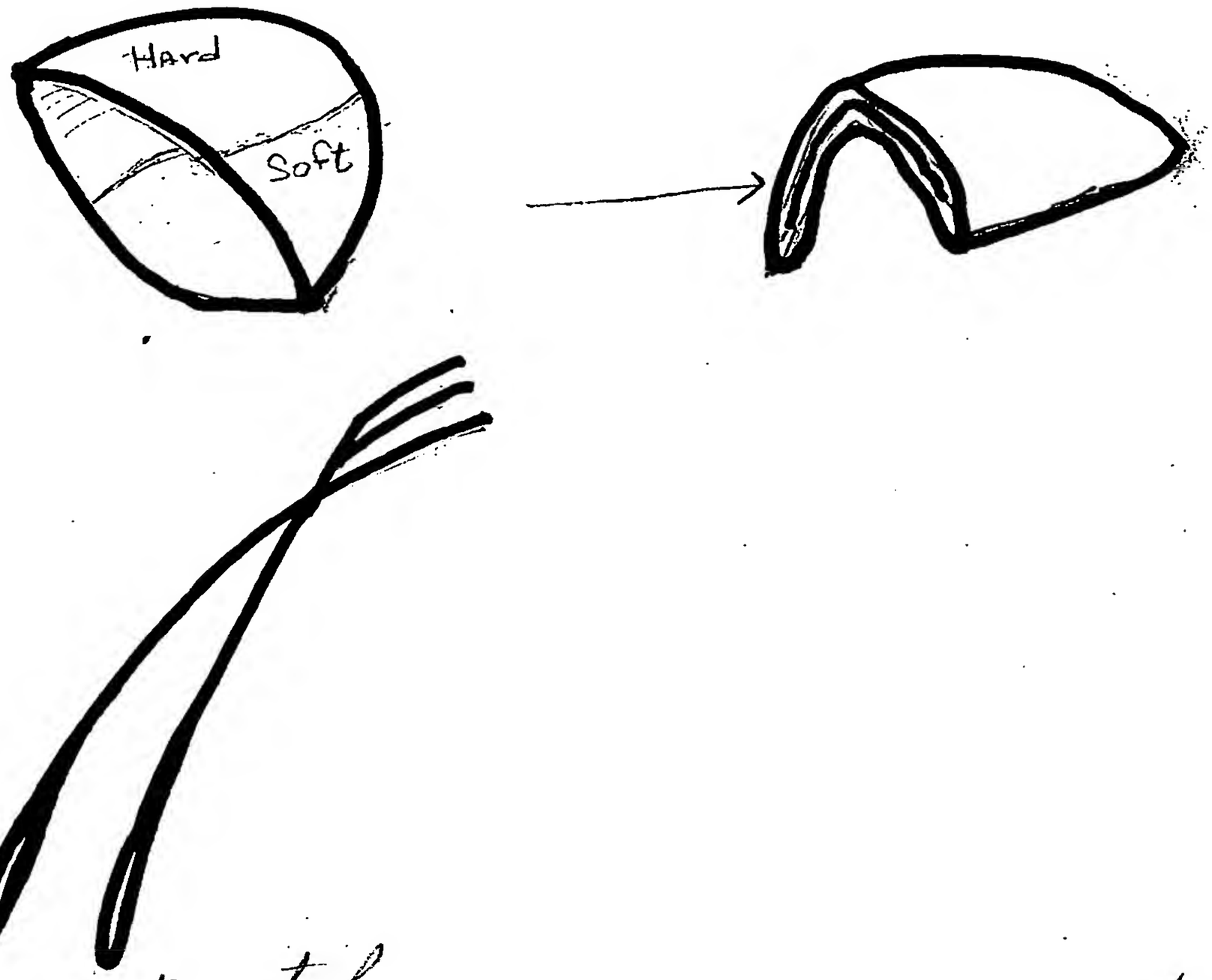
19. A set of instruments, supplied as a set with or without the implant, that allows the surgeon to prepare the acetabulum and femoral head through the arthroscopic portals or the mini-incision for placement of the acetabular implant. (See drawings.)

20. In an alternative embodiment the implant will cover the femoral head with the harder modulus on the superior weight bearing surface and the softer more elastomeric material around the junction with the femoral neck. (See drawing.)

21. An implant as in claim 19 wherein an opening is present to accommodate the ligament of the femoral head.

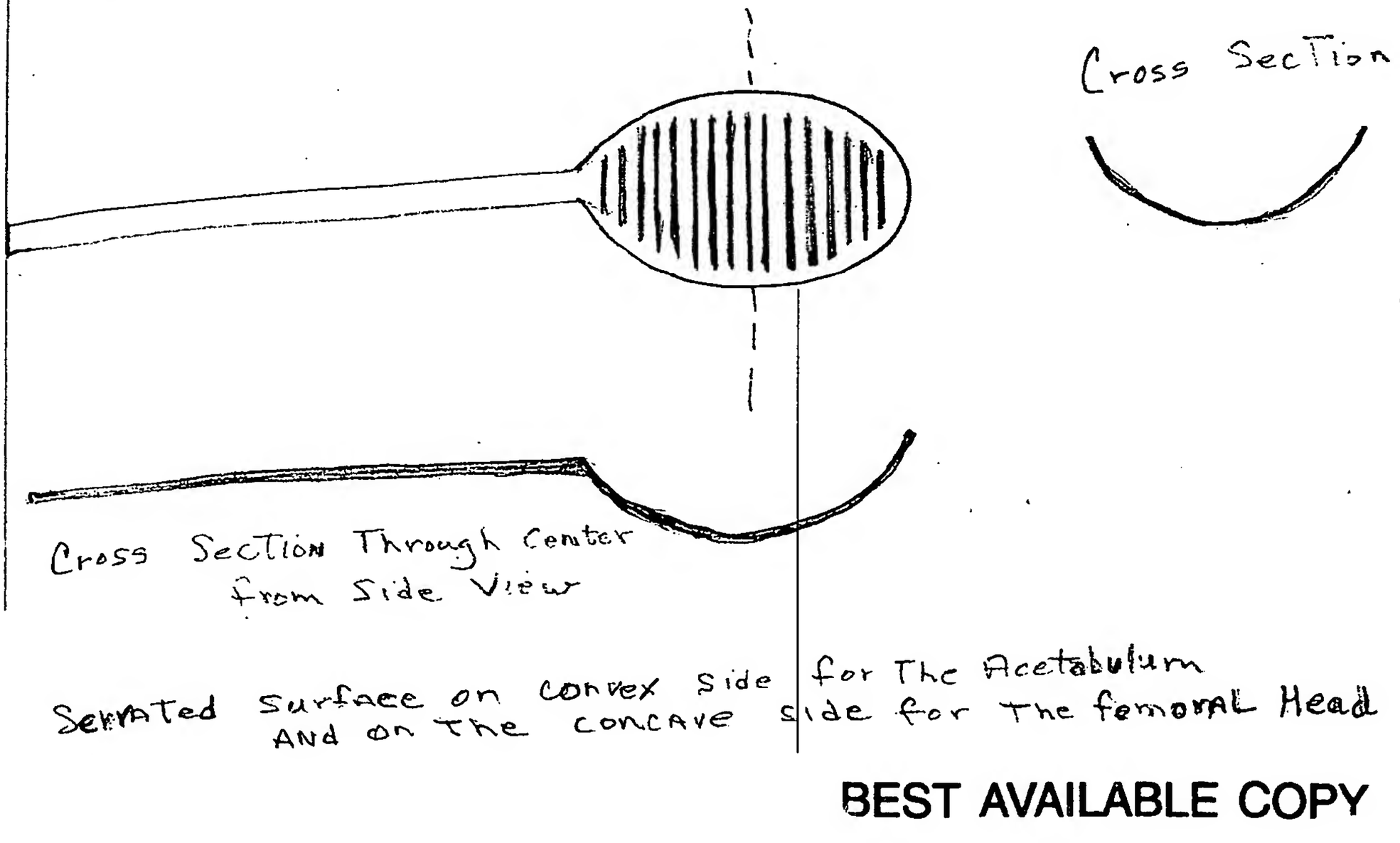
22. An implant as in claim 19 wherein the device is of a single durometer material.

23. An implant as in claims 19 & 21 wherein there are a series (1-5) of barbed anchors that may be press-fit into predrilled holes in the femoral head.



insertion tool

For deployment turn instrument upside down and place double Tongs on low modulus portion in closed position with the single tong at the apex of the high modulus portion of the implant then open tool.



Serrated surface on convex side for The Acetabulum
AND on the concave side for The femoral Head